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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/772,280      | 01/29/2001  | Yves Fouillet        | G-069US02CIP        | 9257             |

23557 7590 04/05/2004

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EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1637

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

## Office Action Summary

### Application No.

09/772,280

### Applicant(s)

FOUILLET ET AL.

### Examiner

Joyce Tung

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-23,25-32 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-23,25-32 and 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The applicant's response (filed December 22, 2003) to the Office Action has been entered. Claims 9-23, 25-32 and 51-60 are pending. Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

1. Applicant's arguments filed in the response (filed December 22, 2003) with respect to claims 9-23, 25-32 and 51-52 have been considered but are moot in view of the new ground(s) of rejection.

### **NEW GROUNDS OF REJECTIONS**

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 9-12, 21-22, 25-32, 51, 55 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bach et al. (6,413,780, issued July 2, 2002).

Bach et al. disclose a method of performing a determination of an item of interest in a sample using a single structure (See the Abstract). The structure will be used for DNA/RNA sample preparation and amplification (See column 4, lines 1-13). A transport system, such as a conveyor or a carousel is used in streamline connected with multiple structures 1a. A relatively large number such as 100, could be operatively connected together (See column 7, lines 29-41). A sample is transferred to a first container in a first process path on the single structure and from the first container, the sample is transferred to a second container in a second process path on the single structure (See column 2, lines 4-12). The first process path 11 includes at least one temperature controller or heater to keep the first process path 11 at a desired temperature, for example 37 degrees Celsius and another portion of the first process path may be maintained at another temperature, for example, 70 degrees Celsius (See column 7, lines 60-67 to column 8, lines 1-2). A thermal regulation device (heating and/ or cooling) is provided with the base 2 (See column 6, lines 13-24). The thermal cycling protocol is provided including the temperature needed for polymerase chain reaction (See column 22, lines 41-67). The containers are moved from one position every selected time interval (See column 7, lines 48-49). The transport system is a conveyor, carouse or the like (See column 7, lines 29-30). It suggests that the transport member is moved along the pathway by reels which frictionally engage the sample transport member. The temperatures used in the protocol are about 50<sup>0</sup>C and about 94<sup>0</sup>C (See column 22, lines 53-59). The protocol is carried out in only one apparatus (See column 19). The pathway is a channel (See fig. 3A)

Bach et al. do not disclose that the protocol is carried out in an atmosphere sufficiently humid to reduce or prevent evaporation of the liquid sample volumes.

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Although Bach et al. do not explicitly disclose that the protocol is carried out in an atmosphere sufficiently humid to reduce or prevent evaporation of the liquid sample volumes, however, the evaporation of the liquid sample volumes is reduced or prevented in a humid atmosphere. It was common knowledge in the art at the time of the instant invention.

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the method of Bach et al. for carrying out a chemical or biochemical protocol because the method of Bach performs approximately 100 or more determinations of items of interest in a sample in an hour (See column 4, lines 1-7). It would be prima facie obvious to carry out the method for a chemical or biochemical protocol by applying the method of Bach et al.

The response argues that the present invention can subject samples to different thermal temperatures in a single temperature regulated zone and there is no requirement for thermal insulation, Bach et al. teach the method using a number of temperature-regulated zones that are thermostated to be maintained at a single temperature. However, the phrase “single temperature regulated zone” of the instant invention is unclear what is meant. The teaching of Bach et al. “one portion of the process path 11 may be maintained at about 37°C, while another portion of the process path 11 may be maintained at about 70°C (See column 7, lines 66-67, to column 8, lines 1-2) is interpreted as a single temperature regulated zone. Moreover, the claims do not indicate whether or not there is a thermal insulation required in either way. The limitations are read in light of the specification and have to be presented in the claims.

The response further argues that the method of instantly claims invention does not use temperature regulated zones that are thermostated to a single temperature; rather, the claimed methods provide that the sample is in at least one temperature regulated zone that cycles between at least two different temperatures. Once again, as discussed above, the phrase “single

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temperature regulated zone” is unclear what is meant. The limitations are read in light of the specification and have to be presented in the claims.

Applicant's arguments filed 12/22/2003 have been fully considered but they are not persuasive as discussed above. The rejection is maintained.

The response also indicates that claims 13-17, 19-23, 25-26, 27, 29 or newly added claim 53-60 were not addressed. Some of these claims are addressed in the rejection above and some are addressed as follows.

4. Claims 13-20, 23, 52-53 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bach et al. (6,413,780, issued July 2, 2002) as applied to claims 9-12, 21-22, 25-32, 51, 55 and 60 above, and further in view of Burns et al. (6271021 issued August 7, 2001).

The teachings of Bach et al. are set forth in section 3 above, and Bach et al. do not disclose that the sample receiving regions comprise a plate, having a plurality of wells and the wells have a film which is hydrophilic to allow the liquid sample in the form of droplets on the surface.

Burn et al. disclose microscale devices comprising microdroplet transport channels, reaction regions, electrophoresis modules and detectors. These elements are microfabricated from silicon and glass substrate. The various components are linked using surface-tension-gradient mechanism (See column 3, lines 54-67). The device is used for nucleic acid amplification (See column 4, lines 6-11). The channels are etched in any number of configurations (See column 5, lines 28-30). It is suggested that the device comprises a substrate

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comprising a plurality of wells. Hydrophilicity-enhancing compounds enhance the hydrophilicity of the transport channel (See column 6, lines 8-16, column 20, claim 3). The devices fabricated with metal resistive heaters. The reaction is covered with mineral oil to prevent evaporation (see column 19, lines 32-38). The microchannel can be preferably 20  $\mu\text{m}$  in depth and 500  $\mu\text{m}$  in width (See column 5, lines 59-64). It is suggested the substrate comprising a filament. The microfluidic device is continuous flow liquid transport (See column 7, lines 62-64).

The device of Burn et al. has gel electrophoresis modules. The electrophoresis was performed with positive electrode to the right (See column 13, lines 32-35) and thinner gels dissipate heat more readily and allow higher voltage to be used. It is suggested that the filament is conducting since there is an electrolyte buffer applied for gel electrophoresis and is heated by passing electric current. Although Burn et al. do not disclose passing electric current is for heating the droplet; the result is that the sample on the gel is heated.

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the device of Bach et al by applying the micro scale devices as taught by Burn et al. because Burn et al. teach that the sample receiving region on a plate substrate having a plurality of wells, the wells have a film which is hydrophilic and the device is in micro scale and the advantage is that each sample droplet is separated from each other so that the risk of contamination is reduced (See column 9, lines 6-8). In addition, the microdroplet transport avoids the current inefficiencies in liquid handling and mixing of reagents (See column 20, lines 16-17). Thus, it has been prima facie obvious to carry out the method by applying a microscale device in which the sample receiving region is on a plate substrate having a plurality of wells and the wells have a film which is hydrophilic to allow forming a droplet on the surface.

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One of ordinary skill in the art at the time of the instant invention would have also been motivated to apply the mineral oil as taught by Burns et al. to cover the sample receiving regions to prevent evaporation of the liquid sample volume in the method of Bach et al. because of the benefit of using the mineral oil in PCR reaction. It would have been prima facie obvious to carry out a chemical or biochemical protocol by applying the method of Bach et al. and in view of the method of Burns et al..

5. Claims 54 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bach et al. (6,413,780, issued July 2, 2002) as applied to claims 9-12, 20-22, 25-26, 28, 30-32, 51, 53 and 60 above, and further in view of Leatti et al. (5,002,870, issued March 26, 1991).

The teachings of Bach et al. are set forth in section 3 above, and Bach et al. do not disclose the thermal transfer member is a metal bar in fluid communication with a plurality water sources that provide water having said at least two temperatures.

Leavitt et al. disclose a method for determining whether a human cell is a hemopoietic cell in which the PCR reaction is performed with temperature cyler at different temperatures (See column 17, lines 1-14). The temperature cyler used in the method has metal bar with water communication.

One of ordinary skill in the art at the time of the instant invention would have been motivated to use the temperature cyler of Leavitt et al. to the method of Bach et al. in order to carry out the chemical or biochemical protocol because the temperature cyler of Leavitt et al. is for a total of 30 cycles and it is convenient. It is prima facie obvious to apply the thermal transfer member, which is a metal bar in fluid communication.

### *Summary*



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6. No claims are allowable.
7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung JT  
March 26, 2004

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

4/1/04